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EXAMINER

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1651

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Please find below and/or attached an Office communication concerning this application or proceeding.



### **DETAILED ACTION**

The amendment filed July 19, 2006, has been received and entered.

Claims 1, 3-5, and 7-19 are pending and examined on the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 9, 11, 13, 15, 16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 15, and 16 are indefinite since the recitation "a moisture content" does not appear to limit the moisture content. It is suggested that the recitation be replaced with "the moisture content." Thus, claims 1, 5, 9, 11, 13, 15, 16, and 18 are rejected under 35 U.S.C. 112, second paragraph.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 9, 11, 13, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,008,647 in view of Shimizu et al. (U.S. Pat. No. 6,258,575) and Ruthven (Encyclopedia of Separation Technology, Vol. 2, John Wiley & Sons, Inc., 1997, page 1072).

EP '647 discloses preparation of an immobilized enzyme for esterification where the enzyme is immobilized on anion exchange resin without drying. The immobilized enzyme is treated with fat and/or oil which are the reaction substrates. See claims 1, 4, 6, and 7 on pages 7 and 8. Example 1 describes the immobilization of 10 g of lipase on 10 g of anion exchange resin, followed by treatment with 40 g of soybean oil (page 5, lines 26, 34, and 37). Thus, the limitations of instant claims 5, 9, and 13 (amount of enzyme is 100 wt. % based on the weight of the carrier) are taught. Soybean oil serves as a mixture of fatty acid triglyceride or fatty acid partial glyceride. In Example 1, the quantity of this oil is 400% by weight based on the weight of the carrier.

Finally, the moisture content of the immobilized enzyme in the '647 invention is given as having a water content of "20% or more by weight" (page 4, lines 35-37, emphasis added), thus satisfying the moisture content limitations indicated in instant claims 15 and 18.

Additionally, it is noted that the reference also teaches the treatment of the carrier with a fat-soluble fatty acid or a derivative thereof before the immobilization step (page 2, paragraph [0012]). Thus, the limitations of instant claim 11 are taught by the reference.

EP '647 does not expressly disclose that the immobilized enzyme is contacted with fatty triglyceride, etc. in the amount of 800 to 5,000% by weight based on the weight of the carrier.

However, Shimizu '575 discloses that 2000 g of soybean-squeezed oil is passed through a column holding 20 g of immobilized lipase. See Example 2, column 8, lines 25-36. The oil mixture is sent through the column multiple times (column 8, line 36 through column 9, line 7, in particular column 8, lines 59-62). The weight of the carrier, an anion exchange resin, may be estimated by performing a calculation using the dimensions of the column (column 8, lines 28-30) and the density range of exchange resin provided by Ruthven (page 1072, first paragraph under "Density and Specific Gravity"). A density of 700 g/L was used for the estimation, and the mass of resin was determined to be about 48 g. Therefore, the amount of soybean-squeezed oil used in Shimizu '575 was about 4100% by weight based on the weight of the carrier. This fits within the range recited in part (ii) of claim 1.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have increased the amount of fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof used for treating the immobilized enzyme as described in EP '647.

One of ordinary skill in the art would have been motivated to do this because it would have improved exposure of the immobilized enzyme to the reaction substrate. Furthermore, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan

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recognizing that the result or effect of the process would differ depending on the amount of fat employed. The artisan of ordinary skill in the art would have recognized the suitability in using the same ratios of oil to carrier as discussed in Shimizu '575 in performing the methods of EP '647, since both function in the same manner (for esterification).

EP '647 also does not expressly disclose that the moisture content of the enzyme is 5% to 50% or 15% to 50% by weight based on the weight of the carrier, after contacting the immobilized enzyme with fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof.

Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have ensured that the moisture content of the immobilized enzyme after contacting with fat/oil is an amount that falls within the range of 5% to 50% or 15% to 50% by weight based on the weight of the carrier.

One of ordinary skill in the art would have been motivated to do this because '647 states that "after the lipolytic enzyme is immobilized by adsorption onto a carrier for immobilization, the initial esterification reaction is conducted by directly bringing the immobilized enzyme **without drying** into contact with the substrate, and removal of this excess water content in this initial esterification requires extra reaction time but can be effected in a considerably shorter time than the time for conventionally conducted drying of the immobilized enzyme" (page 5, lines 3-7, emphasis added). Since reduction of water content is desired, one of ordinary skill in the art would have been motivated to have ensured that the water content is 20% or more by weight, or 40 to 60% by weight, since this was the preferred water content range for the embodiment wherein the drying step proceeds enzyme immobilization (page 4, paragraph [0037]). It would have been applicable to any immobilized enzyme used for decomposing oil and fat, even when

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no active drying step is included in the process of treating immobilized enzyme. Moreover, the selection of the appropriate water content clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the result or effect of the immobilized enzyme on fat/oil decomposition would differ depending on the water content of the treated immobilized enzyme.

Applicant's arguments filed July 19, 2006, have been fully considered but they are not persuasive. Applicant asserts that the Shimizu reference (Shimizu '575) provides no motivation to use an amount of oil in the recited range since the Shimizu reference describes using an amount of oil as a reactant in a hydrolysis reaction, and not as a substrate for treating an immobilized enzyme. However, it is respectfully noted that parent claim 1 does not prohibit a hydrolysis reaction from occurring, and that the methods of Shimizu et al. involving the reaction of soybean oil with immobilized enzyme can be considered methods for treating immobilized enzymes. The reaction of Shimizu '575 where soybean oil is decomposed relates to the same reaction occurring in Example 1 of EP '647 (paragraph [0041] on page 5), which indicates that the 40 g of soybean oil in contact with enzyme immobilized on 10 g of anion exchange resin is decomposed (page 5, line 37). Thus, in modifying EP '647, one of ordinary skill in the art indeed would look to the amount of substrate to be reacted in other references describing the hydrolysis of soybean oil. Given that the decomposition of soybean oil results in a desired product, the greater the amount substrate used, the greater amount of the product obtained. Therefore, contrary to the applicant's assertions, use of a larger amount of substrate would not be a waste of the substrate, and would be economically justifiable by increased production of a desired product.

Though the disclosure of EP '647 teaches that the water content of the immobilized enzyme is 20% or more by weight, or preferably 40-60% by weight prior to contacting with substrate, and the disclosure does not indicate the water content after contact with the substrate, the water content of the immobilized enzyme would not have been expected to increase after contact with the substrate. Moreover, the applicant has provided no evidence that contact with a substrate at any amount would have increased the water content of the immobilized enzyme from this preferred water content range of 40-60%. Even if contact with the amounts of substrate disclosed in EP '647 does not decrease the water content of the immobilized enzyme, at most the water content of the immobilized enzyme would have been expected to remain at 40-60% by weight, which is clearly within the range of 5-50 wt. % recited in the claims.

It is noted that the Sato declaration used an immobilized enzyme with a moisture content of 168% by weight based on the weight of the carrier prior to contacting with substrate (page 2 of declaration filed May 27, 2005). The results discussed in the Sato declaration obtained from using the same amounts of carrier and soybean oil disclosed in EP '647 do not speak to Example 1 of EP '647, since the water content requirements prior to contact with the substrate (40-60% by weight) had not been met. Further still, it is noted that the results of the Sato declaration show that the immobilized enzyme water content decreases after contact with the substrate, therefore, the water content of the EP '647 immobilized enzyme would have inherently decreased from the water content of 40-60%. By contacting the EP '647 immobilized enzyme with a larger amount of substrate, as rendered obvious by combining EP '647 with Shimizu '575, the water content of the immobilized enzyme after contact substrate would have inherently been in the recited range.



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Moreover, contrary to applicant's assertion, as discussed above, the relationship between water content and any result was described in EP '647 (page 5, lines 3-7).

Thus, a holding of obviousness is clearly required.

Claims 1, 5, 9, 11, 13, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,716,610 or U.S. 2003/0096383.

In the response filed on May 27, 2005, applicants note that EP 1,008,647, U.S. 6,716,610, and U.S. 2003/0096383 share common identification of inventors as well as priority claims to Japanese 10-346822 and 10-350920 and the disclosures therein are considered to be equivalent. See discussion above about EP '647.

The '610 patent and '383 application do not expressly disclose that the fatty triglyceride, etc. is 800 to 5,000% by weight based on the weight of the carrier. Furthermore, the references do not expressly disclose that the moisture content of the enzyme is 5% to 50% or 15% to 50% by weight based on the weight of the carrier, after contacting the immobilized enzyme with fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have varied the amount of fatty acid triglyceride, etc. used in the '610 patent or '383 application.

One of ordinary skill in the art would have been motivated to do this since, as stated above, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill. Although Example 3 in each of the references discloses the treatment of immobilized enzyme

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with a fatty acid (aliphatic acid) in the amount of 1000% by weight based on the weight of the carrier, one of ordinary skill in the art would have expected that this amount would have been suitable when the substrate is a fatty triglyceride, a fatty acid partial glyceride or mixtures thereof, instead of a fatty acid. Note that '610 points out that the substrate includes aliphatic acids (column 5, line 6), and that "for preparation of esters having a single aliphatic acid component, partial glycerides and/or triglycerides, these aliphatic acids can be used alone or may be used as a mixture of two or more type thereof" (column 5, lines 10-14). Thus, the aliphatic acids of Example 3 can be substituted with partial glycerides and triglycerides. Finally, the references do not disclose any upper limits for the amounts of fat/oil used to treat immobilized enzyme. Therefore, the reference does not suggest that the amount of fat/oil can not be in the weight range recited in claim 1.

Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have ensured that the moisture content of the immobilized enzyme after contacting with fat/oil is reduced to an amount that falls within the range of 5% to 50% or 15% to 50% by weight based on the weight of the carrier.

One of ordinary skill in the art would have been motivated to do this because '647 (essentially the same disclosure as '610 and '383) discloses that "after the lipolytic enzyme is immobilized by adsorption onto a carrier for immobilization, the initial esterification reaction is conducted by directly bringing the immobilized enzyme **without drying** into contact with the substrate, and removal of this excess water content in this initial esterification requires extra reaction time but can be effected in a considerably shorter time than the time for conventionally conducted drying of the immobilized enzyme" (page 5, lines 3-7, emphasis added). Since

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reduction of water content is desired, one of ordinary skill in the art would have been motivated to have ensured that the water content is 20% or more by weight, or 40 to 60% by weight, since this was the preferred water content range for the embodiment wherein the drying step proceeds enzyme immobilization (page 4, paragraph [0037]). It would have been applicable to any immobilized enzyme used for decomposing oil and fat, even when no active drying step is included in the process of treating immobilized enzyme. Moreover, the selection of the appropriate water content clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the result or effect of the immobilized enzyme on fat/oil decomposition would differ depending on the water content of the treated immobilized enzyme.

A holding of obviousness is clearly required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 9, and 13 are directed to an invention not patentably distinct from claims 1-4 of commonly assigned U.S. Pat. No. 6,716,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims recite the same basic steps as recited in the patented claims, to the extent that the limitations recited in the claims under examination are contained under the patented claims with the exception of the fat/carrier amount recited in claim 1, and the amount of enzyme recited in claim 13. While the weight ranges of enzyme, fatty acid, fatty acid triglyceride, etc. as recited in the claims had not been expressly recited in US '610, the selection of the appropriate amount of fat used to treat immobilized enzyme, and amount of enzyme immobilized on the carrier clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned claims, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the

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invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

In conclusion, claims 1, 5, 9, and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,716,610. The claims are directed to an invention not patentably distinct from U.S. '610.

Applicant's arguments filed July 19, 2006 have been fully considered but they are not persuasive. It would have been obvious to have treated the immobilized enzyme with various amounts of substrate, including the recited amounts, since it is dependent on the amount of product desired to be obtained from hydrolysis by the immobilized enzyme. If the contact amount of 500-8,000 wt. % is used, the moisture content of the enzyme would have inherently been reduced to 5-50 wt.%. Thus, the claimed invention of claims 1, 5, 9, and 13 is obvious over the claims of US '610.

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*Allowable Subject Matter*

Claims 1, 5, 9, 11, 13, 15, 16, and 18 are not allowed. Claims 3, 4, 7, 8, 10, 12, 14, 17, and 19 are allowed. Claim 16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

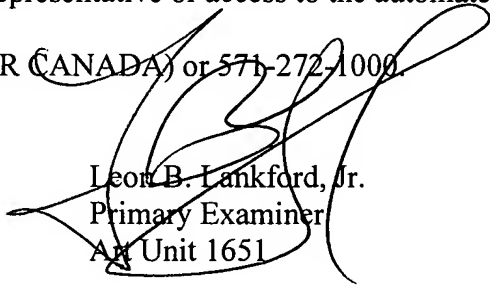
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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